BEIJING REAGENT LATEX PRODUCTS CO., LTD.
ADD: NO.30 SOUTH SANLITUN ROAD, DONGDAQIAO, CHAOWAI, BEIJING, P.R.CHINA.
TEL: 86-10-81502573 FAX: 86-10-81501067 POST CODE: 100020

K012104

AUG 2 1 2001

510K SUMMARY as required by: 807.92 (c)

1.0APPLICANT

Name: BEIJING REAGENT LATEX PRODUCTS CO., LTD.
Add.: NO. 30 SOUTH SANLITUN ROAD, DONGDAQIAO, CHAOWAI BEIJING, 100020 P.R.CHINA
Tel NO. 86-10-81502573
Fax NO. 86-10-81501067

Contact person: MRS. WANG YANNAN
GENERAL MANAGER

2.0 Device trade name: SNOW LOTUS
Common Name: Surgeon's Glove
Classification Name: Powder Free Surgeon's Glove

3.0 Legally marketed device to which the company claiming equivalence:

Class I Surgeon's Glove (Powder Free) 79KGO that meets all the requirement of ASTM D3577.

4.0 Description of the device:

Class I Surgeon's Glove (Powder Free) 79KGO that meets all the requirement of ASTM D3577.

5.0 Intended use of the Device:

A Powder Free Latex Surgical Glove is a disposable device intended in surgical settings for medical purpose that is worn on the hand to provide a barrier against potentially infectious materials and other contaminants.

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6.0 Technological characteristics of the device compared to predicate device.

Measured Parameters of Latex Surgical Gloves Powder Free manufactured by Beijing Reagent Products Co., Ltd.			ASTM D3577-00 Requirement for Latex Surgical Gloves Powder Free
Characteristics	Size	Value	
Length	6.5	Min.265 mm	Min. 265mm
	7	Min.270 mm	Min. 265mm
	7.5	Min.270 mm	Min. 265mm
	8	Min.270 mm	Min. 265mm
	8.5	Min.280 mm	Min. 265mm
	9	Min.280 mm	Min. 265mm
Width	6.5	77-88 mm	83±6 mm
	7	84-94 mm	89±6 mm
	7.5	90-100 mm	95±6 mm
	8	96-108 mm	102±6 mm
	8.5	102-114 mm	108±6 mm
	9	108-120 mm	114±6 mm
Thickness	Cuff	0.14mm	Min.0.10 mm
	Palm	0.18mm	Min.0.10 mm
	Finger	0.22mm	Min.0.10 mm

7.0 PHYSICAL PROPERTIES

	BEFORE AGING		AFTER AGING	
Characteristics	Value	ASTM D3577	Value	ASTM D3577
Tensile Strength	28MPa	24MPa	21MPa	18MPa
Elongation at break %	830%	750%	800%	560%
Modulus at 500% elongation	3MPa	5.5Mpa(max)		

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8.0 PERFORMANCE REQUIREMENT

Characteristics	Related defects	Inspection Level	Level as per ASTM	AQL	AQL as per ASTM D3577
Sterility	Fails sterility	As per ISO	As per USP	N/A	N/A
Freedom from Holes	Holes	G-I	G-I	1.5	1.5
Dimension	Width Length Thickness	S-2	S-2	4	4
Physical Property	Tensile strength Elongation At break before and after aging	S-2	S-2	4	4

POWDER CONTENT

VALUE	ASTM REQUIREMENT
0.38mg/glove	2mg/glove max

PROTEIN CONTENT

VALUE	ASTM REQUIREMENT
31.45 μg/g	≤

BIOCOMPATIBILITY:

VALUE	FDA REQUIREMENT
Biologically Compatible	Biologically Compatible

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9.0 Performance Data:

The performance test data of the powder free surgical gloves manufactured by Beijing Reagent Latex Products Co., Ltd. is given below:

Measured Parameters of Latex Surgical Gloves Powder Free manufactured by Beijing Reagent Latex Products Co., Ltd.		
Characteristics	Size	value
Length	6.5	Min.265 mm
	7	Min.270 mm
	7.5	Min.270 mm
	8	Min.270 mm
	8.5	Min.280 mm
	9	Min.280 mm
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	7.5	90-100 mm
	8	96-108 mm
	8.5	102-114 mm
	9	108-120 mm
Thickness	Cuff	0.14mm
	Palm	0.18mm
	Finger	0.22mm

PHYSICAL PROPERTIES

Characteristic	Before Aging	After Aging
Tensile Strength	28MPa	21MPa
Elongation at break %	830%	800%
Modulus at 500% elongation	3MPa	

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BEIJING REAGENT LATEX PRODUCTS CO., LTD.

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PERFORMANCE REQUIREMENT

Characteristics	Related defects	LEVEL	AQL
Sterility	Fails sterility	N/A	N/A
Dimension	Width Length Thickness	S-2	4.0
Freedom from Holes	Holes	S-4	1.5
Physical Property	Tensile strength Elongation At break before and after aging	S-2	4.0

POWDER CONTENT:
PROTEIN CONTENT: 31.4±0.05 μg/g
BIOCOMPATIBILITY: Biologically Compatible

10. Clinical Data: N/A

11. CONCLUSION OF PERFORMANCE TEST DATA:

The Powder Free Surgical Glove manufactured by BEIJING REAGENT LATEX PRODUCTS CO., LTD.
Meet or exceed the ASTM D 3577
Meet FDA Pin holes Requirement
Meet labeling claim as shown by the Requirment

12. ANY OTHER INFORMATION

Any other information required by FDA regarding product safety and effectiveness will be provided on request.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 1 2001

Mr. Wang Yannan
General Manager
Beijing Reagent Latex Products
No. 30 South Sanlitun Road,
Dongdaqiao
Chaowai, Beijing, P.R.
CHINA

Re: K012104
Trade/Device Name: "Snow Lotus" Powder-Free Latex Surgeon's Gloves
Regulation Number: 878.4460
Regulatory Class: I
Product Code: KGO
Dated: November 30, 2001
Received: July 5, 2001

Dear Mr. Yannan:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to

comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Rebecca Cucenita for

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use Statement

Applicant: Beijing Reagent Latex Products

510(k) Number (if known): K012104

Device Name: Powder Free Latex Surgeon's Gloves

Indications For Use:

A surgeon's glove is a device made of natural or synthetic rubber intended to be worn by operating room personnel to protect a surgical wound from contamination.
(21CFR 878.4460)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K012104